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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,795	12/27/2001	Michael J. Brubaker	P02971	1325
7590 06/30/2004 BAUSCH & LOMB INCORPORATED One Bausch & Lomb Place Rochester, NY 14604-2701			EXAMINER JOYNES, ROBERT M	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/034,795

Applicant(s)

BRUBAKER, MICHAEL J.

Examiner

Robert M. Joynes

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicants' Response and Terminal Disclaimers filed on March 31, 2004.

Terminal Disclaimer

The terminal disclaimer filed on March 31, 2004 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Application Numbers 10/035,095, 10/378,374 and 10/023,391 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (US 5378475) in view of Yaacobi (US 6413540). Smith teaches a sustained release drug delivery device comprising a drug core surrounded by a drug impermeable

player that partially coats the drug core and a second layer that completely coats the core plus the first layer wherein the second layer is permeable to the drug (Col. 4, lines 15-45). The device further comprises a suture tab (Col. 4, lines 44-57). Various drugs can be contained within the core including antiglaucoma drugs, antibiotics, antivirals and antibacterials (Col. 5, line 4 – Col. 6, line 25). The first layer can be made from impermeable polymers and silicone rubbers (Col. 6, lines 30-66). The second layer is permeable to the drug and can be made of various permeable polymers, celluloses and/or polyvinyl alcohols (Col. 8, lines 49-68). The device can be implanted in the eye (Col. 9, lines 42-53). Further, the release rate of the device is controlled by how much of the drug core is coated with the impermeable coating (Col. 7, lines 25-51).

Smith does not teach the permeable portion of the device is prefabricated or that the suture tab has a hole through it in the proximal end. Smith further does not expressly teach that the suture tab is made from silicone. Still further, Smith does not teach that a lip or rim is present.

Yaacobi teaches an ocular implant wherein a lip or rim is created to retain the active agent core in the implant (Col. 4, lines 15-41; Col. 7, lines 47-64).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare a device comprising a drug core surrounded at least partially by a drug impermeable layer and a second portion that is permeable to the drug wherein the device has a sustained release rate. Further, it would have obvious to add a lip or rim to the device in order to retain the active agent core in the implant. It is the position of the Examiner that no criticality is seen in the hole in the suture tab or the

fact that the permeable portion of the device is prefabricated. The suture tab material also does not appear to be critical to the invention. The references teach various polymer and materials that can be used in the device, one being silicone. The device is in the same field of endeavor, has the same elements, and is used in the same manner to achieve the same results. Any difference is a matter of degree and not of kind.

One of ordinary skill in the art would have been motivated to do this to provide a sustained release ocular implant that is suitable to release the drug over a period of time in a fixed location and to retain the active core in the implant. It would be obvious to use any of the suitable materials to create the first layer or the second or the suture tab to achieve the same desired result of a sustained release implantable device. Again, no criticality is placed in the suture tab being silicone as opposed to the PVA recited by the art, or the limitation that the tab must have a hole or the permeable portion being prefabricated.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments with respect to claims 1-31 have been considered but are moot in view of the new ground(s) of rejection.

Applicants argue that the inclusion of a lip or groove are not taught or suggested by the prior art and that the inclusion of such a feature provides unexpected and/or superior results. It is now the position of the Examiner that the new art cited shows a lip or a rim that is used to retain the active core. Both references teach devices that

incorporate the same materials for the same purpose (ocular implants) to achieve the same expected results. Therefore, applicants' arguments are unpersuasive and moot in view of the new grounds for rejection. This action is deemed non-final.

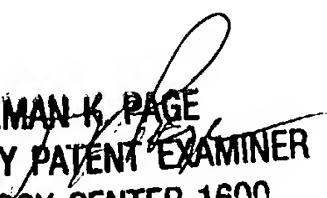
Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (571) 272-0597. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert M. Joynes
Patent Examiner
Art Unit 1615


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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